



Certificate of Analysis

Productname: **Clindamycini hydrochloridum**
Number of analysis/Inspection Code: **1 / KEUR-94200B**
Batchnumber: **12J26-B01-279954** ✓
Reference code / No.:
Analysed according to: **PH.EUR 7.5**



Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification D	White	Conform		Chloride
pH	3,0 - 5,0	4,2		10% m/V
Specific optical rotation		+141		4% m/V; anhydrous
Related substances	Conform	Conform		HPLC
Impurity B	<=2,0	0,7	%	
Impurity C	<=4,0	1,7	%	
Any other impurity	<=1,0	0,8	%	
Total impurities	<=6,0	4,7	%	
Water (Karl Fischer)	3,0 - 6,0	4,1	%	
Sulphated ash	<=0,5	0,1	%	
Residual solvents	CPMP/ICH/283/95	Conform		Data producer
Assay Clindamycin hydrochloride	91,0 - 102,0	95,1	% m/m	GC; anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analyse performed by the authorized lab Proxylabs.

Release:
Drs. M.V. Garcia Alla
Pharmacist - QA Manager / QP

29-03-13

Expiration: 10-2015 ✓

Conclusion: APPROVED

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